DEPARTMENT OF HEALTH AND HUMAN SERVICES

FORM APPROVED

**TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL**

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 04 - 03

2. STATE: MO

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
January 1, 2004

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *( Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
1902(a) (54) and 1927 of the Social Security Act

7. FEDERAL BUDGET IMPACT:
a. FFY Annual savings $ 60 million
b. FFY $

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
3.1-A 15a

9. PAGE NUMBER OF THE SUPERSEDES PLAN SECTION OR ATTACHMENT (If Applicable):
3.1-A 15a

10. SUBJECT OF AMENDMENT:
Preferred Drug List and Supplemental Rebate

11. GOVERNOR'S REVIEW (Check One)

☒ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPE NAME:
Steve Roling

14. TITLE:
Director, Department of Social Services

15. DATE SUBMITTED:
March 30, 2004

16: RETURN TO:
Division of Medical Services
Post Office Box 6500
Jefferson City, MO 65102-6500

**FOR REGIONAL OFFICE USE ONLY**

17. DATE RECEIVED:
March 31, 2004

18: DATE APPROVED:
June 3, 2004

**PLAN APPROVED - ONE COPY ATTACHED**

19. EFFECTIVE DATE OF APPROVED MATERIAL:
January 1, 2004

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:
THOMAS N. LENZ

22. TITLE:
Associate Regional Administrator for DMCH.

23. REMARKS:

04 MAR 31 PM 3:22
CMS - DMSO
REGION VII

FORM HCFA-179 (07-92)

Effective January 1, 1991, the Missouri Medicaid Program covers outpatient drugs, in accordance with Sections 1902 (a) (54) and 1927 of the Social Security Act, which are covered by a national or State agreement, with the following restrictions or exceptions (as indicated by checkmark).

__X__ A. Prior authorization program which complies with Section 1927 (d) (5) of the Social Security Act.
__X__ B. The following drugs are covered, or restricted, as indicated by the checkmark:
__X__ 1. Certain drugs are not covered if the prescribed use is not for medically accepted indication, as defined by Section 1927 (k) (6).
____ 2. Drugs subject to restrictions pursuant to an agreement between a manufacturer and this State authorized by the Secretary under 1927 (a) (1) or 1927 (a) (4).
__X__ 3 Certain products may be limited by on-line clinical or fiscal edits to monitor appropriate utilization and secure cost savings.
__X__ 4. Pursuant to 42 U.S.C. section 1396r-8 the state is establishing a referred drug list with prior authorization for drugs not included on the preferred drug list. The prior authorization process provides for a turn-around response by either telephone or other telecommunications device within twenty-four hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a seventy-two hour supply of medication. Prior authorization will be established for certain drug classes, particular drugs or medically accepted indication for uses and doses. The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.
__X__ 5. The state will meet the requirements of Section 1927 of the Social Security Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for the supplemental rebate program for Medicaid recipients:
a) The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.
b) A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on March 30, 2004 and entitled, "State of Missouri Supplemental Rebate Agreement," has been authorized by CMS.
c) Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.
d) All drugs covered by the program, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

__X__ C. The following drugs or classes of drugs, or their medical uses, as indicated by a checkmark, are excluded from coverage or otherwise restricted:
__X__ 1. Agents when used for anorexia or weight gain.
__X__ 2. Agents when used to promote fertility.
__X__ 3. Agents when used for cosmetic purposes or hair growth.
__X__ 4. Agents when used for symptomatic relief of cough and colds.
__X__ 5. Agents used to promote smoking cessation.
__X__ 6. Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
__X__ 7. Nonprescription drugs (see attached).
____ 8. Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or his designee.
__X__ 9. Drugs described in section 107 (c) (3) of the Drug Amendments of 1962 and identical, similar, or related drugs (within the meaning of section 310.6 (b) (1) of title 21 of the Code of Federal Regulations (DESI drugs).
__X__ 10. Barbiturates (see attached).
__X__ 11. Benzodiazepines (see attached).
__X__ 12. Case/Disease Management implemented by physician/pharmacist teams for patients determined at risk using approved risk assessment model.

# MISSOURI SUPPLEMENTAL DRUG-REBATE AGREEMENT

CONTRACT #_____

## 1 PARTIES/PERIOD

1.1 This Supplemental Drug-Rebate Agreement ("Agreement") is made and entered into this _____day of _____ 2004, by and between Missouri ("State"), represented by the Division of Medical Services ("Division"), and _____ ("Manufacturer"), Labeler Code(s) _____. The parties, in consideration of the covenants, conditions, agreements, and stipulations expressed in this Agreement, do agree as follows:

## 2 PURPOSE

2.1 It is the intent of this Agreement that the State will receive Supplemental Rebates, in addition to the rebates received under Manufacturer's Centers for Medicare and Medicaid Services ("CMS") Agreement, pursuant to Section 1927 of the Social Security Act (42 U.S.C. §1396r-8), for the Manufacturer's Supplemental Covered Product(s) quarterly utilization in the Missouri Medicaid Program in which there is Medicaid federal financial participation. The parties also intend for this Agreement to meet the requirements of federal law at Section 1927 of the Social Security Act (42 U.S.C. §1396r-8).

## 3 DEFINITIONS

3.1 'Average Manufacturer Price' (AMP) means Manufacturer's price for the Covered Product(s). AMP will be calculated as specified in Manufacturer's CMS Agreement.

3.2 'Best Price' means, with respect to a Single Source Drug or Innovator Multiple Source Drug of a Manufacturer, the lowest price available from the Manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within the United States, excluding: (a) any price charged on or after October 1, 1992, to the Indian Health Services, the Department of Veterans Affairs, a State home receiving funds under Section 1741 of Title 38, United States Code,

the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of Section 1927 of the Social Security Act; (b) any prices charged under the Federal Supply Schedule of the General Services Administration; (c) any prices used under a State Pharmaceutical Assistance Program; and (d) any depot prices and single award contract prices, as defined by the Secretary of any agency of the Federal Government. "Best Price" shall: (a) be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section); (b) be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and (c) not take into account prices that are merely nominal in amount.

3.3 'Covered Product(s)' means the pharmaceutical product(s) of the Manufacturer pursuant to Section 1927 of the Social Security Act (42 U.S.C. §1396r-8).

3.4 'CMS Agreement' means the Manufacturer's drug rebate contract with the Centers for Medicare & Medicaid Services (CMS), formerly known as the Health Care Financing Administration, entered into pursuant to Section 1927 of the Social Security Act (42 U.S.C. §1396r-8).

3.5 'CMS Basic Rebate' means, with respect to the Covered Product(s), the quarterly payment by Manufacturer pursuant to Manufacturer's CMS Agreement, made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act [42 U.S.C. §1396r-8(c)(1) and 42 U.S.C. §1396r-8(c)(3)].

3.6 'CMS CPI Rebate' means, with respect to the Covered Product(s), the quarterly payment by Manufacturer pursuant to Manufacturer's CMS Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act [42 U.S.C. §1396r-8(c)(2)].

3.7 'CMS Unit Rebate Amount' means, the unit amount computed by CMS to which the Medicaid utilization information may be applied by states in invoicing the Manufacturer for the rebate payment due.

3.8 'Manufacturer' means, for purposes of this Agreement, the non-state party to this Agreement, which may be a pharmaceutical manufacturer, labeler or other entity not prohibited by law from entering into this Agreement, as identified in Section 1.1 of this Agreement.

3.9 'Net Cost Per Unit' or 'Net Cost' means, with respect to the Supplemental Covered

Product(s), the amount per NDC# agreed upon by the parties to this Agreement and set forth in the attached Addendum A.

3.10 'Pharmacy Provider' means an entity licensed or permitted by state law to dispense legend drugs, and enrolled as a Missouri Medicaid provider.

3.11 'CMS Rebate' means, with respect to the Covered Product(s), the quarterly payment by Manufacturer to states as detailed in Sections 3.5, 3.6, and 4.1 of this Agreement.

3.12 'State Utilization Data' means the data used by the Division to reimburse pharmacy providers under the Missouri Medicaid Program. State Utilization Data excludes data from covered entities identified in Title 42 U.S.C. §256b(a)(4) in accordance with Title 42 U.S.C. §256b(a)(5)(A) and 1396r-8(a)(5)(C).

3.13 'Supplemental Covered Product(s)' means the Manufacturer's Covered Product(s), as listed in the attached Addendum A, that are the subject of this Agreement and for which Manufacturer has agreed to pay Supplemental Rebates. These are the Manufacturer's Covered Product(s) that received preferred status on the Missouri Medicaid Preferred Drug List as a result of this Agreement.

3.14 'Supplemental Rebate Amount Per Unit' means, with respect to the Supplemental Covered Product(s), the amount(s) by NDC#, as specified in the attached Addendum A, that the Manufacturer has agreed to reimburse the Division per unit of Supplemental Covered Product in accordance with the formula detailed in the attached Addendum A.

3.15 'Rebate Summary' means the report itemizing the State Utilization Data supporting the Division's invoice for Supplemental Rebates. The Rebate Summary will comply in all respects with requirements for Medicaid Utilization Information in the CMS Agreement.

3.16 'Supplemental Rebate' means, with respect to the Supplemental Covered Product(s), the quarterly payment by Manufacturer pursuant to Section 4.2 of this Agreement.

3.17 'Wholesale Acquisition Cost' or 'WAC' means the Manufacturer's U.S. Dollar wholesale acquisition price in effect on the last day of the applicable quarter on a unit basis, as published by a third party source, such as First Databank, for each product and is understood to represent the Manufacturer's published price for a drug product to wholesalers. Any dispute as to the applicable WAC shall be conducted in accordance with the dispute provisions contained herein.

## 4 MANUFACTURER'S RESPONSIBILITIES

4.1 Manufacturer will calculate and provide the Division a CMS Rebate for the Covered Product(s), which includes the CMS Basic Rebate and CMS CPI Rebate, as appropriate. The CMS Rebate represents the discount obtained by multiplying the units of the Covered Product(s) reimbursed by the Division in the preceding quarter by the per unit rebate amount provided to the Division by CMS. CMS will calculate the CMS Rebate amount in accordance with Manufacturer's CMS Agreement. Manufacturer's obligation for CMS Rebates will continue for the duration of the Manufacturer's CMS Agreement and is not affected by this Agreement.

4.2 In addition to the CMS Rebates described in Sections 3.5, 3.6, and 4.1 of this Agreement, Manufacturer will remit to the Division Supplemental Rebates for the Supplemental Covered Product(s) utilization in the Missouri Medicaid Program. The Supplemental Rebates will be calculated on a calendar quarter basis and provided via an invoice to the Manufacturer's CMS financial contact. The Supplemental Rebate for the quarter will be determined by multiplying the number of units of each of the Supplemental Covered Product(s) (by NDC#) reimbursed by the Division, for Missouri Medicaid utilization, in the preceding quarter by its corresponding Supplemental Rebate Amount Per Unit, which is determined pursuant to the terms of the Missouri Supplemental Rebate Agreement Addendum A attached hereto, and summing the products of said multiplication(s). The Manufacturer's obligation for Supplemental Rebates will continue for the duration of this Agreement.

4.3 The Manufacturer will pay the Supplemental Rebate(s) set forth in this Agreement for utilization of the Supplemental Covered Product(s) during the fourteen (14) month period beginning the 1st day of May, 2004, and ending the 30th day of June, 2005, as well as for any additional periods during which this Agreement remains in effect.

4.4 The quarters to be used for calculating the Supplemental Rebates in Section 4.2 of this Agreement will be those ending on March 31, June 30, September 30, and December 31 of each calendar year during the term of this Agreement.

4.5 Manufacturer shall submit the Supplemental Rebate payment within 38 days of the Manufacturer's receipt of the Rebate Summary from the Division.

4.6 Manufacturer will pay the Supplemental Rebate(s), including any applicable interest in accordance with Section 1903 (d)(5) of the Act. Interest on the Supplemental Rebates payable under Section 4.2 of this Agreement begins accruing 38 calendar days from the postmark date of the Division's invoice and supporting Rebate Summary sent to the Manufacturer and interest will continue to accrue until the postmark date of the Manufacturer's payment. The interest rate will be calculated as required under federal guidelines for rebates described in Sections 3.5, 3.6 and 4.1. If the Division has not received the Supplemental Rebates payable under Section 4.2 of this Agreement, including any applicable interest, within 180 days of the postmark date of the Division's invoice and supporting Rebate Summary sent to Manufacturer, this Agreement will be deemed to be in default and State may terminate this Agreement by providing Manufacturer with written notice of termination. Said notice of termination shall cite this section of the Agreement and the termination shall not affect Manufacturer's obligation to remit Supplemental Rebates for utilization of Manufacturer's Supplemental Covered Products that occurred prior to the termination of this Agreement.

4.7 Manufacturer agrees to continue to pay Supplemental Rebates on the Supplemental Covered Product(s) for as long as this Agreement is in force and State Utilization Data shows that payment was made for the Supplemental Covered Product(s), regardless of whether the Manufacturer continues to market the Supplemental Covered Product(s). Notwithstanding the above, in the event Manufacturer sells or transfers its right to sell a Supplemental Covered Product(s) and ceases to manufacture, sell, label, and market the Supplemental Covered Product(s), Manufacturer may assign its obligations under this Agreement with respect to said Supplemental Covered Product(s) to the Supplemental Covered Product(s)'s new owner. However, Manufacturer shall continue to have liability under this Agreement for the same period of time that Manufacturer has liability for CMS Rebates under Manufacturer's CMS Agreement for said assigned Supplemental Covered Product(s). Manufacturer shall provide the Division with notice of the sale of said Supplemental Covered Product(s) concurrent with Manufacturer's notice to CMS. If a Supplemental Covered Product is assigned pursuant to this Section, Manufacturer shall provide the Division with an update of the information contained in Section 9.3 herein with respect to the Supplemental Covered Product(s)'s new owner.

4.8 Unless notified otherwise, Manufacturer will send Supplemental Rebate payments by certified mail, return receipt requested, or via overnight courier to the following address:

Rebate Unit
Department of Social Services
Division of Medical Services
P.O. Box 6500
615 Howerton Court
Jefferson City, Missouri 65102-6500

5 DIVISION RESPONSIBILITIES

5.1 The Division will classify Manufacturer's Supplemental Covered Product(s) as "preferred" in the Missouri Medicaid Preferred Drug List. The Division may determine, as a result of a therapeutic class review, that prior authorization is required for all preferred drugs in a therapeutic class. If prior authorization is required for any Supplemental Covered Product, the Division will comply with all provisions of section 1927(d) of the Social Security Act applicable to Prior Authorization programs. Notwithstanding the above, the Division retains the right to remove Manufacturer's Supplemental Covered Product(s) from its Preferred Drug List. Said removal shall relieve Manufacturer of its obligation to pay Supplemental Rebates for utilization of the affected Supplemental Covered Product(s) that occurs subsequent to such removal. State's clinical edit and step edit programs shall not be affected by this Agreement.

5.2 The Division will provide aggregate State Utilization Data to Manufacturer on a quarterly basis. This data will be based on paid claims data (data used to reimburse pharmacy providers) under the Missouri Medicaid Program, will be consistent with any applicable Federal or State guidelines, regulations and standards for such data, and will be the basis for the Division's calculation of the Supplemental Rebate(s).

5.3 The Division will maintain those data systems necessary to calculate the Supplemental Rebate(s). In the event material discrepancies are discovered, the Division will promptly justify its data or make an appropriate adjustment, which may include a credit as to the amount of the Supplemental Rebates, or a refund to Manufacturer as the parties may agree.

5.4 The Division shall maintain electronic or other claims records, for such time periods as are required by CMS to permit verification of the calculation of CMS Rebates, to permit Manufacturer to verify through an audit process the Rebate Summaries provided by the Division. Any audit conducted pursuant to this Section 5.4 shall be conducted by independent auditors, at Manufacturer's expense, during regular business hours and not more often than one (1) time per calendar year. The independent auditors shall provide at least thirty (30) days prior written notification of their intent to audit. The Division shall make available to the independent auditors such records as are required to demonstrate the accuracy of the claims submitted to the Manufacturer under this Agreement. The independent auditors may be required to enter into confidentiality agreements with the State and Manufacturer as necessary to comply with state and federal laws and regulations governing the privacy of individual or other health information or information that is proprietary and/or confidential. The independent auditors will not be provided access to information related to other manufacturers.

5.5 Upon implementation of this Agreement, and from time to time thereafter, the Division and Manufacturer may meet to discuss any data or data system improvements which are necessary or desirable to ensure that the data and any information provided by the Division to Manufacturer are adequate for the purposes of this Agreement.

5.6 The State shall obtain CMS approval of its state Medicaid plan, including the State's establishment of its Medicaid preferred drug list/supplemental-drug rebate program under which the Supplemental Rebates contracted for herein will be paid. Manufacturer shall not be required to remit any Supplemental Rebates that have accrued and are due until State has obtained the CMS approval provided for in this Section. The Division will provide Manufacturer, within thirty (30) days of receipt, a copy of the CMS document (usually approval of the State's State Plan Amendment) authorizing State's Medicaid preferred drug list/supplemental-drug rebate program.

## 6 DISPUTE RESOLUTION

6.1 In the event that in any quarter a discrepancy in State Utilization Data is questioned by the Manufacturer, which the Manufacturer and the Division in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy to the Division.

6.2 If the Manufacturer in good faith believes the State Utilization Data is erroneous, the Manufacturer shall pay the Division that portion of the Supplemental Rebate claimed, that is not in dispute by the required date in Section 4.6. The balance in dispute, if any, will be paid by the Manufacturer to the Division by the due date of the next quarterly payment after resolution of the dispute.

6.3 The Division and the Manufacturer will use their best efforts to resolve any discrepancy within 60 days of receipt of written notification. Should additional information be required to resolve disputes, the Division will cooperate with the Manufacturer in obtaining the additional information.

6.4 In the event that the Division and the Manufacturer are not able to resolve a discrepancy regarding State Utilization Data as provided for in Sections 6.1 through 6.3, the Manufacturer may request a reconsideration of the Division's determination within 30 days after the end of the 60 day period identified in Section 6.3. The Manufacturer shall submit to the Division, along with its written request, its argument in writing, along with any other materials, supporting its position.

6.5 In the event that the Division and the Manufacturer are unable to resolve a discrepancy regarding State Utilization Data as provided for in Sections 6.1 through 6.4, the parties will utilize the same State procedure that is used to resolve disputes under the Medicaid Rebate program, consistent with CMS' *Best Practices Guide for Dispute Resolution Under the Medicaid Drug Rebate Program.*